

NTP Board of Scientific Counselors
Peer Review of
NTP-CERHR Briefs
May 2005

The National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) was established in 1998 to provide a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental or occupational chemicals. The CERHR convenes Special Emphasis Panels to prepare expert panel reports on chemicals selected for evaluation. Following completion of an expert panel report, the NTP prepares a NTP-CERHR monograph that contains the NTP Brief, the expert panel's report, and any public comments received on the expert panel report. The NTP Brief presents the NTP's interpretation of the potential for the chemical to adversely affect human reproductive health or child development.

In December 2004, the Office of Management and Budget (OMB) issued the Final Information Quality Bulletin for Peer Review (OMB Bulletin).¹ The OMB Bulletin establishes minimum standards for peer review "of scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the federal government" and provides defined standards for disseminations considered "influential scientific information"² or "highly influential scientific information."³ The NTP has reviewed the OMB Bulletin and, in consultation with Department of Health and Human Services (HHS) and the National Institutes of Health (NIH), evaluated the CERHR's process for development of the NTP-CERHR monographs. Specifically, the NTP believes the NTP Brief is subject to the OMB Bulletin. The NTP would clarify that its opinion regarding the potential hazardous nature of a chemical evaluated by CERHR is not at issue, rather, the OMB Bulletin addresses peer review of the scientific information upon which that opinion is based.

The NTP has carefully examined the NTP Briefs for previously evaluated chemicals and recognizes that while all NTP Briefs contain scientific information, they would not necessarily all meet a specific classification of "influential scientific information" or "highly influential scientific information" as defined by the OMB Bulletin. It should be noted that the NTP, on a case-by-case basis, would determine the classification of a brief for a specific chemical. However, considering all ramifications of the standards outlined in the OMB Bulletin, the NTP has submitted to HHS and NIH for their review a proposed process for peer review of NTP Briefs based upon their classification as "influential scientific information."

¹ 70FR2666, included in your background materials for peer review

² "means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions"

³ "influential scientific information the the agency or Administrator [of the Office of Information and Regulatory Affairs in OMB] determines to be a scientific assessment that: (i) could have a potential impact of more than \$500 million in any year, or (ii) is novel, precedent-setting, or has significant interagency interest."

The NTP proposes to present an outline of that peer review process to the NTP Board at the June meeting. It is our intent to send additional information to the NTP Board prior to the meeting once review by HHS and NIH is completed.